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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,216	05/30/2001	Charles A. Nicolette	GZ 2101.00	8103

7590

01/26/2005

Antoinette F. Konski
Bingham McCutchen LLP
Three Embarcadero Center, Suite 1800
San Francisco, CA 94111

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,216	NICOLETTE, CHARLES A.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 4-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/27/01, 4/15/02, 02/15/03</u> | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A (seq. alignment)</u> |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I encompassing claims 1-3, with species election of SEQ ID NOs 3, and 5 in the reply filed on 06/10/2004 is acknowledged. The traversal is on the ground(s) that the examination of all pending claims would not put a serious burden on the examiner because all independent claims recite 5 specific sequences; the sequences in the claims are not complicated R groups in chemical structure, but a straight sequences; up to 10 nucleotide sequences should be examined according to MPEP section 803.04. This is not found persuasive because group I is drawn to peptides as the active ingredients in the composition, while group I is drawn to host cells as the active ingredients, and group III is drawn to method.

Searching of composition comprising peptides and composition comprising host cells, and method of using a composition together would impose a serious search burden. In the instant case, the search of the peptides and the host cells are not coextensive. The inventions have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. A journal articles disclosing the peptides sequence might not disclose host cells expressing the peptides.

As for groups I, and III, the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

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include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-9 are pending, and claims 1-3 are examined on merits.

As for the election of species, since the elected species SEQ ID NOs: 3, and 5 are free of art, the species election is withdrawn and search is expanded to include other species in the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the same native ligand" in line 3. There is insufficient antecedent basis for this limitation in the claim. For compact prosecution purpose, the Office assumes "the same native ligand" to be the art-known a human eukaryotic initiation factor 3 p40 (elf3-p40) for the art search purpose, since the specification at page 6 line 2 discloses "elf3" as only native ligand. However, this treatment does not relieve applicant the burden of responding this rejection.

Claim 1 recites the limitation "said immunogenic ligand" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim. For the purpose of this

Office action, the Office will interpret the limitation as one of said two immunogenic ligands in line 1 of claim 1 is selected from the 5 different Markush groups. However, this treatment does not relieve applicant the burden of responding to this rejection.

The dependent claims 2, and 3 are also rejected because the dependent claims include the rejected limitation, but do not further clarify the rejected limitation.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 as written, do not sufficiently distinguish over nucleic acids, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed composition and the naturally occurring composition. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified" in front of "at least two immunogenic ligands" in line 1 of claim 1. See MPEP 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Asano et al., J Biol Chem. 1997 Oct 24;272(43):27042-52).

Claim 1 is interpreted as drawn to a composition comprising at least two immunogenic ligands, wherein one ligand of said at least two immunogenic ligands is selected from an immunogen comprising SEQ ID NOs: 3, 5, 7, 9, or 11, wherein said ligands elicit an immune response against elf3-p40. Since claim 1 as currently construed does not have a transitional phrase (note the limitation "selected from the group consisting of" SEQ ID NOs:3, 5, 7, and 11 in claim 1 is a Markush format indicating the alternate choice, not a transitional phrase), the scope of the claimed "immunogenic ligand" in lines 3-4 is broadly interpreted as drawn to an immunogen **comprising** SEQ ID NO:11.

Asano et al., at page 27047 (note Fig. 3B) teach a composition comprising at least two immunogenic ligands, wherein one ligand of said immunogenic ligands is an immunogen comprising SEQ ID NO: 11. Note the attached sequence alignment (Exhibit A) showing that instant SEQ ID NO:11 is fragment of elf3-p40 shown in Fig 5B, 2nd last line in underlined amino acids residues of 242 to 250.

As for the limitation that said ligand elicit an immune response against the same native ligand, the antibody (note page 27043, right column, under the heading "EXPERIMENTAL PROCEDURES", also note page 27049, right column, 2nd para) is elicited immune response against elf3-p40 (note Fig. 2, and 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asano et al.,(cited above) in view of US 5789200 A (Aug. 4, 1998).

The claims are interpreted as drawn to composition comprising at least two immunogenic ligands in a pharmaceutically acceptable carrier.

As stated above in 102 (b) rejection, Asano et al., teach a composition comprising at least two immunogenic ligands. See the further detail above.

Asano et al., do not teach a pharmaceutically acceptable carrier or carrier.

However, US 5789200 teaches that "pharmaceutically acceptable carriers" are "saline, buffered saline, dextrose, water, glycerol, ethanol, and combinations thereof. The formulation should suit the mode of administration. Selection of an appropriate

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carrier in accordance with the mode of administration is routinely performed by those skilled in the art." Note column 31, lines 45-51.

Therefore, it would have been obvious to formulate the immunogen of Asano et al., comprising instant SEQ ID NO:11 in a pharmaceutically acceptable carrier with a reasonable expectation of success before administering to a subject to elicit an immune response, and one of ordinary skill would be motivated to use pharmaceutically acceptable carrier such that a subject does not get sick by an unsuitable carrier for in vivo administration.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

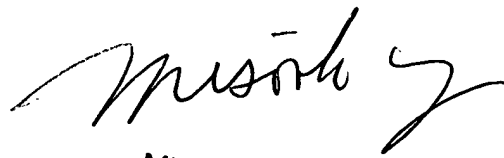
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

A handwritten signature in black ink, appearing to read "Misook Yu", with a stylized flourish at the end.

MISOOK YU
PATENT EXAMINER

GenCore version 5.1.6
Copyright (c) 1993 - 2005 Compugen Ltd.

OM protein - protein search, using sw model

Run on: January 12, 2005, 19:38:08 ; Search time 85 Seconds
(without alignments)
60.922 Million cell updates/sec

Title: US-09-870-216C-11

Perfect score: 43

Sequence: 1 NLQLMDRV 9

Scoring table: BLOSUM62

Gapop 10.0 , Gapext 0.5

Searched: 1825181 seqs, 575374646 residues

Total number of hits satisfying chosen parameters: 1825181

Minimum DB seq length: 0

Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%

Maximum Match 100%

Listing first 45 summaries

Database : UniProt 02.1*

1: uniprot_sprot.*

2: uniprot_trembl.*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query Match	Length	DB ID	Description
1	43	100.0	352	1 IF33 HUMAN	O15372 homo sapien
2	43	100.0	352	2 Q6P9U8	Q6P9U8 rattus norv
3	43	100.0	352	2 AAH60586	AAH60586 rattus no
4	43	100.0	352	2 CAG33187	CAG33187 homo sapi
5	38	88.4	335	2 Q6P381	Q6P381 xenopus tro
6	38	88.4	335	2 AAH64151	AAH64151 xenopus t
7	38	88.4	352	1 IF33 MOUSE	Q91W42 mus musculu
8	38	88.4	352	2 Q8BTX5	Q8BTX5 mus musculu
9	37	86.0	473	2 Q8DJU7	Q8DJU7 synchococc
10	36	83.7	196	2 Q94BU3	Q94BU3 arabidopsis
11	36	83.7	311	2 Q8LAP2	Q8LAP2 arabidopsis
12	36	83.7	311	2 Q9LMB2	Q9LMB2 arabidopsis
13	35	83.7	342	2 Q9LMB3	Q9LMB3 arabidopsis
14	35	81.4	133	2 Q9NZ20	Q9NZ20 homo sapien
15	35	81.4	180	2 Q9Y221	Q9Y221 homo sapien
16	35	81.4	180	2 Q9WV50	Q9WV50 rattus norv
17	35	81.4	180	2 Q9CXK8	Q9CXK8 mus musculu
18	35	81.4	180	2 Q9D1B4	Q9D1B4 mus musculu
19	35	81.4	180	2 AAH59114	AAH59114 rattus no
20	35	81.4	180	2 BAD05056	BAD05056 homo sapi
21	35	81.4	1742	2 Q7TT21	Q7TT21 mus musculu
22	35	81.4	1742	2 AAH60701	AAH60701 mus muscu
23	35	81.4	1809	1 TSC2 RAT	P49816 rattus norv
24	35	81.4	1814	1 TSC2 MOUSE	Q61037 mus musculu
25	34	79.1	149	2 Q6Y1Z6	Q6Y1Z6 pagrus majo
26	34	79.1	149	2 AAP20218	AAP20218 pagrus ma
27	34	79.1	285	2 Q31388	Q31388 cyprinus ca
28	34	79.1	560	2 Q73MF8	Q73MF8 treponema d
29	34	79.1	560	2 AAS12067	AAS12067 treponema
30	34	79.1	681	1 RPOC_ANTFO	Q85C16 anthraceros
31	34	79.1	808	2 Q6BZ11	Q6BZ11 debaryomyce

RESULT 1

ID	IF33_HUMAN	STANDARD;	PRT;	352 AA.
AC	O15372;			
DT	30-MAY-2000 (Rel. 39, Created)			
DT	30-MAY-2000 (Rel. 39, Last sequence update)			
DT	05-JUL-2004 (Rel. 44, Last annotation update)			
DE	Eukaryotic translation initiation factor 3 subunit 3 (eIF-3 gamma)			
DE	(eIF3 p40 subunit) (eIF3h).			
GN	Name=eIF3S3;			
OS	Homo sapiens (Human)			
OC	Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;			
OC	Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.			
OX	NCBI_TaxID=9606;			
RN	[1]			
RP	SEQUENCE FROM N.A.			
RC	TISSUE=Liver;			
RX	MEDLINE=98001678; PubMed=9341143;			
RA	Aeano K., Vornlocher H.-P., Richter-Cook N.J., Merrick W.C.,			
RA	Hinnebusch A.G., Hershey J.W.B.;			
RT	"Structure of cDNAs encoding human eukaryotic initiation factor 3			
RT	subunits. Possible roles in RNA binding and macromolecular assembly.";			
RL	J. Biol. Chem. 272:27042-27052(1997).			
RN	[2]			
RP	SEQUENCE FROM N.A.			
RC	Schmidt O.G., von Holtum D., Gross S., Horsthemke B., Lueddecke H.-J.;			
RA	"The gene encoding the p40 subunit of the translation initiation			
RT	factor eIF3 has 8 exons, maps to the langer-Giedion syndrome region on			
RT	chromosome 8q24, but is not the TRPS gene.";			
RL	Submitted (SEP-1998) to the EMBL/GenBank/DBJ databases.			
RN	[3]			
RP	SEQUENCE FROM N.A.			
RC	TISSUE=Lung;			
RX	MEDLINE=22388257; PubMed=12477932; DOI=10.1073/pnas.242603899;			
RA	Strausberg R.L., Feingold E.A., Grouse L.H., Derge J.G.,			
RA	Klausner R.D., Collins F.S., Wagner L., Shenmen C.M., Schuler G.D.,			
RA	Altschul S.F., Zeeberg B., Buetow K.H., Schaefer C.F., Bhat N.K.,			
RA	Hopkins R.F., Jordan H., Moore T., Max S.I., Wang J., Hsieh F.,			
RA	Diatchenko L., Marusina K., Farmer A.A., Rubin G.M., Hong L.,			
RA	Stampert M., Soares M.B., Bonaldo M.F., Casavant T.L., Scheetz T.E.,			
RA	Brownstein M.J., Usdin T.B., Toshiyuki S., Carninci P., Prange C.,			
RA	Raha S.S., Loquellano N.A., Peters G.J., Abramson R.D., Mullaly S.J.,			
RA	Bosak S.A., McEwan P.J., McKernan K.J., Malek J.A., Gunaratne P.H.,			
RA	Richards S., Worley K.C., Hale S., Garcia A.M., Gay L.J., Hulyk S.W.,			
RA	Villalón D.K., Muzny D.M., Sodergren E.J., Lu X., Gibbs R.A.,			
RA	Fahey J., Helton E., Kettman M., Madan A., Rodrigues S., Sanchez A.,			
RA	Whiting M., Madan A., Young A.C., Shevchenko Y., Bouffard G.G.,			
RA	Blakesley R.W., Touchman J.W., Green E.D., Dickson M.C.,			
RA	Rodriguez A.C., Grimwood J., Schmutz J., Myers R.M.,			
RA	Butterfield Y.S.N., Krzywinski M.I., Skalska U., Smailus D.E.,			
RA	Schuerch A., Schein J.E., Jones S.J.M., Marra M.A.;			
RT	"Generation and initial analysis of more than 15,000 full-length human			
RT	and mouse cDNA sequences.";			
RL	Proc. Natl. Acad. Sci. U.S.A. 99:16899-16903(2002).			

ALIGNMENTS

32	34	79.1	964	2	Q7UJ58
33	34	79.1	1116	2	O18415
34	34	79.1	1127	2	Q9VM62
35	34	79.1	1127	2	AAF52463
36	33	76.7	257	2	Q9MBR8
37	33	76.7	245	2	Q6F7M9
38	33	76.7	509	2	Q8TWC3
39	33	76.7	874	2	Q9XGC1
40	32	74.4	35	2	Q88G77
41	32	74.4	99	2	Q7SFM5
42	32	74.4	99	2	CAE76192
43	32	74.4	175	2	Q6Z8S5
44	32	74.4	175	2	BAC86871
45	32	74.4	181	2	Q6BGJ7

Exhibit A

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X

